Investigator's Checklist for IND Application Submission

Cover Letter
Form 1571
Form 1572
Form 3674
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Introductory Statement and General Investigational Plan
Chemistry, Manufacturing, and Control Information
Pharmacology Toxicology Information
Investigator's Brochure
Clinical Protocol(s)
Summary of Previous Human Experience with the Investigational New Drug
Additional Information, if applicable (e.g. drug dependence and abuse potential, pediatric studies, etc.)
Other Relevant Information, if applicable or if requested by FDA

Notes: